UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et al., ex rel.* ADAM HART,

Plaintiff,

v.

MCKESSON CORPORATION, *et al.*,

Defendants.

15-CV-0903 (RA)

OPINION & ORDER

RONNIE ABRAMS, United States District Judge:

Plaintiff-Relator Adam Hart has filed this *qui tam* action against McKesson Corporation, McKesson Specialty Distribution LLC, and McKesson Specialty Care Distribution Corporation (collectively "McKesson") on behalf of the United States of America, the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Virginia, Washington, and the District of Columbia (collectively "the States"). Hart alleges that McKesson offered business-management tools to specialty oncology practices that joined programs requiring them to purchase a substantial proportion of their drugs from McKesson, and that doing so violated the Anti-Kickback Statute ("AKS"). 42 U.S.C. § 1320a-7b(b). Any claims for reimbursement submitted by these practices to the United States or the States, he asserts, were tainted by the kickback scheme and thus in violation of the federal False Claims Act, 31 U.S.C. § 3729 *et seq.* ("FCA"), and the corresponding state laws, *see* Am. Compl. ¶¶ 1, 3.

McKesson has moved to dismiss, arguing that: (1) Hart fails to plausibly allege that the business-management tools constituted remuneration under the AKS; (2) Hart fails to plausibly allege that Defendants acted with the requisite scienter; and (3) Hart fails to plead the fraudulent scheme with the particularity required by Federal Rule of Civil Procedure 9(b). For the reasons that follow, Defendants' motion to dismiss is granted, though Plaintiff is granted leave to amend.

BACKGROUND[1]

I. The Parties

McKesson Corporation is a Delaware corporation headquartered in Irving, Texas. Am. Compl. ¶ 15. McKesson sells pharmaceuticals, medical supplies, and related services to health care providers. *Id.* ¶¶ 2, 40. McKesson Corporation is the parent company of the other McKesson Defendants, "which are wholly-owned direct or indirect subsidiaries of McKesson Corporation." *Id*. ¶ 15. McKesson Specialty Distribution LLC is a Delaware limited liability company and a wholly-owned subsidiary of McKesson Corporation. *Id* ¶ 16. McKesson Specialty Care Distribution Corporation is a Delaware corporation and also a wholly-owned subsidiary of McKesson Corporation. *Id*.[2] Hart alleges, upon information and belief, that during the relevant time period, McKesson Specialty Health ("MSH") was a business unit of McKesson Corporation, McKesson Specialty Care Distribution Corporation, and McKesson Specialty Distribution LLC. *Id*. Through MSH, McKesson operated as a wholesale distributor, buying specialty drugs and reselling them to customers across the country. *Id.* ¶¶ 2, 16-17, 40.

Plaintiff-Relator Hart was employed by McKesson from August 2011 until September 2014 as a Business Development Executive ("BDE") in its Specialty Health business unit. *Id.* ¶ 14.

[1] The facts in this section and throughout are taken from Plaintiff's amended complaint (the "complaint") and are assumed to be true for purposes of this motion. *See Stadnick v. Vivint Solar, Inc.*, 861 F.3d 31, 35 (2d Cir. 2017).
[2] In or around May 2013, McKesson Specialty Care Distribution JV LLC merged with McKesson Specialty Care Distribution Corporation, which became the surviving company. Am. Compl. ¶ 16.

His responsibilities included generating new business opportunities among community-based oncology practices in the southeastern United States. *Id*. Once a customer was recruited, Hart would provide services for the first year, after which a "McKesson Account Executive" was assigned. *Id*. The McKesson Account Executive was responsible for maintaining and increasing sales, but Hart remained in touch with practices through "sales meetings, sales calls, requests for assistance from other personnel, and communications with coworkers." *Id*.

II. McKesson's Oncology Business

As relevant here, MSH provided "specialty pharmaceuticals and services to community oncology practices." *Id.* ¶ 47.[3] The specialty drugs used in cancer treatment are complex to manufacture, require special handling, and, as a result, are more expensive than other drugs. *Id*. ¶ 39. Some oncology practices obtain the drugs from a specialty pharmacy, which then bills patients' insurers. *Id.* ¶ 41. Others opt to purchase drugs from wholesalers like McKesson, provide those drugs to their patients, and then bill the patients' insurers themselves. *Id*.

In 2014, the oncology business was MSH's largest line of business by revenue, generating $7 billion of MSH's $9 billion in annual revenue. *Id.* ¶ 47. There were two divisions of the oncology business, and Hart worked in the "open market" division, which operated as a traditional drug wholesaler and distributor. *Id*. ¶¶ 47-48. The allegations in the complaint are limited to the practices of the open market division. *Id*. ¶¶ 48-49.

III. The Business-Management Tools

Hart's claims are based primarily on McKesson's usage of two business-management tools—the Margin Analyzer and the Regimen Profiler—which were offered almost exclusively to

[3] Community oncology practices provide oncology care in an "office setting," as opposed to providers who operate in a hospital setting. Am. Compl. ¶ 41.

practices that committed to purchasing a significant portion of their drugs from McKesson. *Id.* ¶ 69.

A. The Margin Analyzer

Beginning in approximately 2011, McKesson offered its customers "complimentary access" to the Margin Analyzer. *Id.* ¶ 52.[4] Among other things, the tool allowed oncology practices to compare the reimbursement rates of interchangeable drugs. *Id.* ¶¶ 54-55. McKesson had identified "therapeutically interchangeable" choices for ten categories of drugs commonly used by oncology practices. *Id.* ¶ 60. For any given category, the Margin Analyzer relied on pricing and reimbursement data to determine which of the similar drugs would yield the highest profit for the practice. *Id.* ¶¶ 61, 63. McKesson employees input reimbursement data from Medicare and private insurers, allowing the tool to analyze the profitability of different drugs based on a patient's insurer. *Id.* ¶¶ 57-59, 61-63.

Hart's complaint includes the following illustration of the tool's utility. The Margin Analyzer listed five "therapeutically interchangeable options" for parenteral irons. *Id.* ¶ 77. In Q2 2012, McKesson's data showed that, for Medicare-insured patients, the difference between acquisition cost and reimbursement price was significantly greater for one brand of parenteral irons, Feraheme, than other brands. *Id.* For Summit Cancer Care in Savannah, Georgia, specifically, a switch from prescribing only Infed parenteral irons (margin of $15.20 per dose), to a mix of 80% Feraheme (margin of $88.50 per dose) and 20% Infed would increase annualized net profits by $10,560. *Id.* ¶ 78. The Margin Analyzer excerpt below shows the type of data comparisons available to McKesson representatives and the practices:

[4] The complaint also alleges that Brian Larson, who developed the Margin Analyzer, continued to maintain it until at least June 2015, Am. Compl. ¶ 52, and that between 2012 and November 30, 2017, McKesson's customers submitted "hundreds of millions of dollars" in false claims to Medicare after having received either the Margin Analyzer or Regimen Profiler, *id.* ¶ 121.

					COST / DOSE			MEDICARE				
Drug	Dose (mg's)	Dose Cost	Dose ASP+6%	Dose AWP	Drug	Admin	Cost/cycle Total	Drug	Admin	MDCR Allowable Total	Net Profit $	Net Profit %
INFED 50MG/	1000	$ 246.75	$ 241.94	$ 377.00	$ 246.75	$ 100	$ 347	$ 241.94	$ 120	$ 362	$ 15.2	4%
DEXFERRUM	1000	$ 235.62	$ 241.94	$ 377.00	$ 235.62	$ -	$ 236	$ 241.94	$ -	$ 242	$ 6.3	3%
NULECIT 12.5	1000	$ 351.89	$ 309.28	$ 610.56	$ 351.89	$ -	$ 352	$ 309.28	$ -	$ 309	$ (42.6)	-14%
FERAHEME 3	1020	$ 559.18	$ 647.70	$ 948.60	$ 559.18	$ -	$ 559	$ 647.70	$ -	$ 648	$ 88.5	14%
VENOFER 20	1000	$ 320.00	$ 290.00	$ 430.00	$ 320.00	$ -	$ 320	$ 290.00	$ -	$ 290	$ (30.0)	-10%

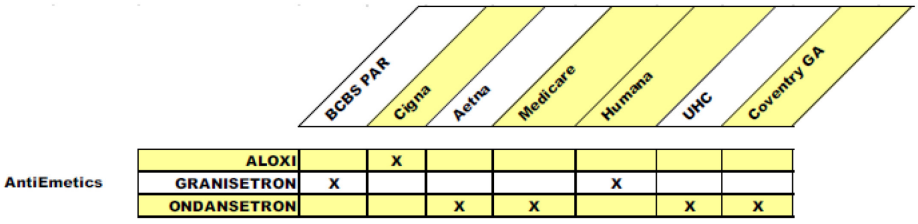
See Am. Compl. Ex. 4 (Q2 2012 SCC Margin Analyzer).

The Margin Analyzer was used not only to compare the cost and profit margin on a per drug, per insurer basis, but also to give forward-looking recommendations based on that data. BDEs or Account Executives were able to forecast various scenarios by inputting different drug mixes or potential payors, and then used those findings to aid the practices in choosing a drug distribution that was most profitable. *See* Am. Compl. ¶¶ 73-78. Because the Margin Analyzer allowed practices to instantly compare the profit margin of one drug versus others in the same category, a BDE or Account Executive could identify areas with large profit opportunities. *See id.* McKesson personnel met with their customers at "Quarterly Business Reviews" to review the Margin Analyzer and to provide "a detailed analysis of the practice's finances and business operation." *Id.* ¶ 65.

In order to generate these results, the Margin Analyzer required data, including: the fee schedules published quarterly by the Centers for Medicare and Medicaid Services ("CMS"); the customer's quarterly purchase records; the prices at which McKesson sold its drugs; and the fee schedules of relevant private insurers. *Id.* ¶¶ 56-58. McKesson employees would gather and input this data into spreadsheets for each practice, and update them on a quarterly basis as the data changed. *Id.*

Because different insurers reimbursed different drugs at different rates, a drug most profitable for a Medicare patient may not be as profitable for a patient with a given private insurer.

The Margin Analyzer not only accounted for the different reimbursement amounts offered by different insurers, but synthesized the data into a "cheat sheet" page that recommended the most profitable drug in each category, by payor. *See id.* ¶¶ 81-82; *id.* Ex. 1 Q4 2012 SCC Margin Analyzer; *id.* Ex. 5 Q1 2013 SCC Margin Analyzer. The "cheat sheet" generated for the Summit Cancer Care in Q4 of 2012, for example, recommended one of three different antiemetic drugs depending on whether the patient was covered by BlueCross BlueShield, Cigna, or Medicare. *See* Am. Compl. at ¶ 82; Q4 2012 SCC Margin Analyzer.



As with all the data in the Margin Analyzer, McKesson would update these sheets every quarter as reimbursement rates changed. Am. Compl. ¶¶ 84-85. The most cost-effective drugs were subject to change each quarter. Compare Q4 2012 SCC Margin Analyzer with Q1 2013 SCC Margin Analyzer.

McKesson used the Margin Analyzer in three contexts: to acquire new customers and/or retain existing customers, *id.* ¶ 64; to provide consultation and financial advice to existing customers at in-person "Quarterly Business Reviews," *id.* ¶ 65; and to encourage the purchase of new drugs (or drugs with new pricing), *id.* ¶ 66.

B. The Regimen Profiler

The Regimen Profiler worked in much the same way as the Margin Analyzer, but rather than calculate the margins for an individual drug, it calculated costs for the whole treatment regimen. *Id.* ¶¶ 5, 96. Oncology practices typically incur significant non-drug related costs in the administration of cancer therapy, such as the cost of preparing or administering the treatments, so

the price of the drug itself is only one component of the overall cost. *Id.* ¶¶ 97, 99. The Regimen Profiler filled this gap—calculating profit margins for the course of treatment, including non-drug costs. *Id*. Insurers reimbursed these non-drug costs as well, and so the Regimen Profiler, like the Margin Analyzer, calculated the profitability of each treatment regimen on a provider-by-provider basis. *Id*. ¶ 99. The tool was designed to be used in conjunction with the Margin Analyzer to understand a practice's overall profitability and/or potential profitability. *See id.* Ex. 3 (Margin Analyzer Sales Sheet). McKesson employed the Regimen Profiler in the same manner as the Margin Analyzer—to pitch new customers and retain existing ones. Am. Compl. ¶ 101. Moreover, as with the Margin Analyzer, McKesson made an "explicit contractual promise" only to commitment program customers to provide the Regimen Profiler free of charge. *Id.*

C. McKesson's Offer of the Business Management Tools to Commitment Program Customers

Hart alleges that these tools were provided, for free, on a quarterly basis, to a number of oncology practices in the Southeast. They were not, however, distributed to all of McKesson's customers. Instead, the Margin Analyzer and Regimen Profiler were offered, "with few (or no) exceptions. . . *only* to physician practices that contracted to join the Onmark Select, Prime, or MVP programs." *Id*. ¶ 69 (emphasis in original). The Onmark Select, Prime Membership, and McKesson Value Program ("MVP") (collectively the "commitment programs"), required practices to purchase a certain volume of their drugs from McKesson. *Id*. ¶ 68. The Onmark Select program required use of McKesson as the "primary wholesale supplier" for branded and generic drugs, while the Prime and MVP programs required a commitment to purchase approximately 90% to 95% of the practice's branded and generic drugs from McKesson. *Id*.

If they did not join one of the commitment programs, oncology practices were still able to purchase drugs from McKesson. But MSH did not allow non-commitment program customers to

access the business-management tools. *Id*. ¶¶ 70, 101. One practice—Hematology Oncology of the Treasure Coast—that sought to end its purchase commitment with McKesson was explicitly told that if it did so, it would lose access to the Margin Analyzer. *Id*. ¶ 70.

Hart names twelve practices that were offered the tools for free and signed commitment programs with McKesson: Summit Cancer Care (Savannah, GA) Premier Oncology Center (Naples, FL), Spalding Oncology (Griffin, GA), Florida Medical Clinic (Land O' Lakes, FL), Noor Merchant, MD (Sebastian, FL), Suncoast Medical Clinic (St. Petersburg, FL), Oncology Hematology Associates of West Broward (Tamarac, FL), ICON Oncology (Jacksonville, FL), Emerald Coast Cancer Center (Ft. Walton Beach, FL), Citrus Hematology and Oncology (Inverness, FL), Central Florida Cancer Institute (Davenport, FL), and Alabama Cancer Care (Gadsden, AL). *Id*. ¶ 53. Each of these practices were, allegedly,

> offered the Margin Analyzer and/or the Regimen Profiler for free as an inducement to make a purchase commitment from McKesson. During the sales pitch to these practices, McKesson populated the Margin Analyzer with the practices' specific drug utilization information to demonstrate the utility of the Margin Analyzer. Each of these physician practices signed purchase commitments with McKesson and informed McKesson that the Margin Analyzer and, in some instances, the Regimen Profiler were key components of their decision to commit to buying specialty drugs from McKesson.

Id. ¶ 71. With respect to the Regimen Profiler, Hart states that Summit Cancer Care, Premier Oncology Center, Florida Medical Clinic, Emerald Coast Cancer Center, and Southern Hematology and Oncology were also "offered the Regimen Profiler as an inducement to make a purchase commitment from McKesson, subsequently signed purchase commitments, and used the Regimen Profiler." *Id.* ¶ 101.

Without specifying any particular oncology practices outside of Florida, Georgia, or Alabama, Hart further alleges that this conduct occurred nationwide. *Id.* ¶¶ 71, 122. Because he knew McKesson's general policies, and had experience with other BDEs from national sales

conferences, Hart alleges "scores of other providers across the country" were provided the Margin Analyzer and Regimen Profiler for free as an inducement to join the commitment programs. *Id.* ¶¶ 71, 114, 121-122.

Hart's complaint also contains allegations that suggest McKesson knew that the Margin Analyzer and Regimen Profiler were valued by its customers. Sales training materials attached to the complaint emphasized the importance of the Margin Analyzer to retaining customers. *See id.* Ex. 2 (Margin Analyzer Flyer); Margin Analyzer Sales Sheet. And McKesson purportedly believed that the tools were important to both enhancing its profitability and creating "stickiness" among its customers. Am. Compl. ¶ 70; *id.* Ex. 8 at 8-9 (2014 South Region Meeting Presentation). Hart also references internal communications in which McKesson concluded at least some customers stayed with McKesson, over lower cost providers, in order to retain access to the Margin Analyzer. Am. Compl. ¶ 64. The company prepared a customer testimonial video dedicated to the business-management tools, touting their potential value to community oncology practices. *Id.* ¶ 109.

McKesson's view that the tools were important to customer acquisition and retention was purportedly emphasized at its in-person sales conferences. At those events, executives from McKesson made clear that the Margin Analyzer should be at the center of sales pitches to new customers. *Id.* ¶¶ 70, 107, 114. Indeed, according to Hart, the Margin Analyzer and Regimen Profiler were so central to the company's sales direction that one BDE was fired for failing to sufficiently highlight the tools. *Id.* ¶ 107.

IV. The Anti-Kickback Statute and False Claims Act

The AKS and FCA work in conjunction to create a private right of action for violation of the federal criminal anti-kickback statute. The FCA creates liability for any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or

approval; knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(A)-(B). Claims are defined as "any request or demand for money from an officer, agent, employee, or contractor of the United States." 31 U.S.C. § 3729(b)(2)(A).

The AKS prohibits any individual or entity from "knowingly and willfully offer[ing] or pay[ing] any remuneration . . . directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . or arrange for or recommend purchasing . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. §1320a-7b(b)(2)(B). Claims resulting from an AKS violation constitute "a false or fraudulent claim" for the purposes of the FCA. 42 U.S.C. §1320a-7b(g); *see also United States v. Novartis Pharms. Corp.*, No. 13-CV-3700 (KMW), 2020 WL 1436706, at *1 (S.D.N.Y. Mar. 24, 2020).

V. Procedural History

Plaintiff filed his initial complaint on February 6, 2015. Because the action was brought under the False Claims Act, the complaint was placed under seal to afford the Government an opportunity to intervene. *See* 31 U.S.C. § 3730(b)(2). The Government ultimately declined to intervene, and the complaint was unsealed as of May 29, 2020. Plaintiff then amended his complaint (the "complaint"). In it, Hart alleges that McKesson's practice of offering the business-management tools exclusively to customers who joined its commitment programs resulted in the submission of false claims to the government. Am. Compl. ¶¶ 120-122. Because this policy constitutes an AKS violation, he asserts, claims submitted for reimbursement to government health care programs in connection with the violation are "false" under the FCA. *Id.* ¶¶ 8, 123. Hart also alleges that McKesson knew that providing any valuable services to induce purchases was

unlawful and that it also knew the customers to whom it offered the Margin Analyzer and Regimen Profiler were submitting claims to federal and state health care programs. Am. Compl. ¶¶ 7, 117.

The complaint includes one claim based on Defendants' purported FCA violation (Count 1), *id.* ¶¶ 124-131; 31 U.S.C. § 3729(a)(1)(A)–(B), as well as causes of action under the False Claims Act analogs of 28 States and the District of Columbia (Counts II-XXIX, "the state analogs"), based on the same conduct.

Defendants now move to dismiss the complaint pursuant to Federal Rules of Civil Procedure 9(b) and 12(b)(6). For the reasons that follow, the motion is granted.

LEGAL STANDARD

When considering a motion to dismiss under 12(b)(6), a court must "accept all allegations in the complaint as true and draw all inferences in the non-moving party's favor." *LaFaro v. New York Cardiothoracic Grp., PLLC*, 570 F.3d 471, 475 (2d Cir. 2009).[5] A complaint must be dismissed if it fails to state a claim upon which relief can be granted. Fed R. Civ. P. 12(b)(6). The complaint must "contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A complaint that offers only "'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action, will not do.'" *Id*. (quoting *Twombly*, 550 U.S. at 555). Nor will a complaint suffice if it contains only "'naked assertion[s]' devoid of further 'factual enhancement.'" *Id.* (quoting *Twombly*, 550 U.S. at 557).

Because FCA claims "fall within the express scope of Rule 9(b)," *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476-77 (2d Cir. 1995) (per curiam), a relator must "state with particularity the circumstances constituting fraud," Fed. R. Civ. P. 9(b). While the circumstances

[5] Unless otherwise indicated, case quotations omit all internal citations, quotations, footnotes, and alterations.

of the fraud must be pled with particularity, "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally" under Rule 9(b). Fed. R. Civ. P. 9(b). Rule 9(b) demands specificity, but "it does not elevate the standard of certainty that a pleading must attain beyond the ordinary level of plausibility." *United States ex rel. Chorches for Bankr. Est. of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 88 (2d Cir. 2017). Where an FCA claim is predicated on a violation of the AKS, both the FCA and AKS violations must be pled in compliance with Rule 9(b). *United States v. Novartis Pharms. Corp.*, No. 13-CV-3700 (KMW), 2020 WL 1436706, at *3 (S.D.N.Y. Mar. 24, 2020) (citing *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617-18 (2d Cir. 2016) and *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 513-14 (S.D.N.Y. 2014)). Claims under the FCA state analogs must also satisfy Rule 9(b). *Novartis*, 2020 WL 1436706, at *3 (citing *United States ex. rel. Arnstein v. Teva Pharms. USA, Inc.*, No. 13-CV-3702, 2016 WL 750720, at *11 (S.D.N.Y. Feb. 22, 2016) ("*Arnstein*")).

DISCUSSION

In its motion to dismiss, McKesson contends that Hart's complaint fails in three respects: (1) it fails to plausibly allege that the business-management tools constituted remuneration; (2) it fails to plausibly allege that Defendants acted with the required scienter; and (3) it fails to plead the fraudulent scheme with particularity. For the reasons that follow, the Court finds that the tools, as described, plausibly constitute remuneration, but agrees with Defendants that Hart has failed to include sufficient allegations to support an interference that McKesson acted with knowledge that its conduct was unlawful. The claims must therefore be dismissed.

I. Hart has Plausibly Alleged that the Margin Analyzer and Regimen Profiler Constitute Remuneration

The AKS proscribes the knowing and willful offer or payment of "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in

kind," in order to induce the purchase of drugs or services that will ultimately be reimbursed by a federal health care program. 42 U.S.C. § 1320a-7b(b)(2). Where a purchase has been tainted by illegal remuneration, the claim is a false or fraudulent claim within the meaning of the FCA. 42 U.S.C. § 1320a-7b(g); *see also Novartis*, 2020 WL 1436706, at *1.

A. The Scope of "Remuneration"

Remuneration is required to establish a violation of the AKS, but the term is not defined by the statute. Nonetheless, courts have consistently found that the term has an "expansive scope," and can encompass anything of value. *State v. MedImmune, Inc.*, 342 F. Supp. 3d 544, 552 (S.D.N.Y. 2018) (collecting cases); *United States ex rel. Wood v. Allergan, Inc.*, 246 F. Supp. 3d 772, 805-06 (S.D.N.Y. 2017) *rev'd on other grounds*, 899 F.3d 163 (2d Cir. 2018); *United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 756 (S.D.N.Y. 2015); *U.S. v. Matthew Blair*, No. CR ELH-19-00410, 2021 WL 4339132, at *15-*16 (D. Md. Sept. 23, 2021). This interpretation accords with the plain meaning of remuneration, and with the purpose of the 1977 amendment that altered the scope of the AKS by adding "remuneration." *Pfizer Inc. v. United States Dep't of Health & Hum. Servs.*, No. 20-CV-4920 (MKV), 2021 WL 4523676, at *11 (S.D.N.Y. Sept. 30, 2021) *appeal filed*, No. 21-2764 (October 29, 2021) (discussing the definition of "remuneration"); *Blair*, 2021 WL 4339132, at *15-*16 (same); *see also OIG Anti-Kickback Provisions*, 56 Fed. Reg. 35952, 35958, 1991 WL 304395 (July 29, 1991) ("Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever."). Before the 1977 amendment, the AKS only applied to "bribes, kickbacks, and rebates." *See* 56 Fed. Reg. 35952, 35958; *see also* Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175 (1977) (codified as amended at 42 U.S.C. §§ 1320a-7b(b)(1)(A)-(B)). The term "any remuneration" was added to ensure that, regardless of the particular type of value exchanged, the substance of an arrangement or service

would be controlling rather than merely the form. *See* H.R. REP. 95-393, pt. 2, at 53, 1977 WL 16075 (1977); *see also* 56 Fed. Reg. 35952, 35958 ("The statute's legislative history . . . makes clear that the fundamental analysis required of a trier of fact is 'to recognize that the substance rather than simply the form' of a transaction should be controlling." (internal quotation omitted)); 123 Cong. Rec. 30,280 (1977) (statement of Rep. Rostenkowski, Chairman of the House Committee on Ways and Means and principal author of the 1977 amendments) ("In broadening these criminal provisions, your committee sought to make clear that kickbacks are wrong no matter how a transaction might be constructed to obscure the true purpose of a payment.").[6]

Drawing on the 2003 OIG Compliance Program Guidance for Pharmaceutical Manufacturers and subsequent OIG advisory opinions, McKesson argues that Hart must plead that the Margin Analyzer and Regimen Profiler had "substantial and independent value" in order to constitute remuneration under the AKS. Plaintiff counters that, even assuming without deciding that application of the higher "substantial and independent value" standard is proper here, the tools as alleged in the complaint nonetheless constitute things of "substantial and independent value."

B. Whether the Tools Constitute Remuneration

Accepting as true the facts in the complaint, and drawing all inferences in Plaintiff's favor, as required at this stage, *Doe v. Columbia Univ.*, 831 F.3d 46, 48 (2d Cir. 2016), Plaintiff has plausibly alleged that the Margin Analyzer and Regimen Profiler have substantial value apart from

[6] Courts have also relied on the definition of remuneration in the civil health care fraud statute to determine the scope of the term in the criminal statute. *See United States v. Narco Freedom, Inc.*, 95 F. Supp. 3d 747, 757 n.4 (S.D.N.Y. 2015) (discussing the differences between the civil and criminal statutes and collecting cases in which courts have relied on the definition in § 1320a-7a(i)(6) in interpreting § 1320a–7b(b)). In the civil statute, remuneration is defined as "transfers of items or services for free or for other than fair market value." 42 U.S.C. § 1320a-7a(i)(6); *see also U.S. ex rel. Fair Lab. Practices Assocs. v. Quest Diagnostics Inc.*, No. 05-CV-5393 (RPP), 2011 WL 1330542, at *2 (S.D.N.Y. Apr. 5, 2011), *aff'd*, 734 F.3d 154 (2d Cir. 2013) ("The AKS defines remuneration as including 'transfers of items or services for free or for other than fair market value.' 42 U.S.C. § 1320a–7a(i)(6)."). Remuneration as used in the criminal statute, moreover, has a more expansive scope than the civil analog. *See Narco Freedom, Inc.*, 95 F. Supp. 3d at 756-57.

the products offered by McKesson. The "30-second Elevator Pitch" from McKesson's sales materials on the Margin Analyzer, for example, reads as follows:

> McKesson Specialty Health's Margin Analyzer is a spreadsheet-based tool that provides oncology practices with a detailed view of their current drug purchasing and reimbursement trends, serving as an important tool for successful financial management. The analysis provides insight to specific cost, reimbursement and utilization by drug code, as well as trending by quarter to aid in budget forecasting — all of which helps provide a better understanding of which drug choices make the most financial sense for a practice. The Account Executive, in collaboration with a Clinical Specialist when requested, reviews the customized data with practices on a quarterly basis, allowing for regular touch-points with decision makers and an opportunity to introduce additional products and services that can help further enhance a practice's vitality.

Margin Analyzer Sales Sheet at 1. Hart has alleged that these tools were central to McKesson's sales pitches to new customers, and that at least a dozen oncology practices "signed purchase commitments with McKesson and informed McKesson that the Margin Analyzer and, in some instances, the Regimen Profiler were key components of their decision to commit to buying specialty drugs from McKesson." Am. Compl. ¶ 71.

In response, McKesson makes several arguments: that the tools lacked substantial value because the underlying data was available for free; that the tools did not have value because they provided only potential cost-savings; and that the tools were not independent of McKesson's product offerings, and thus had no value to non-McKesson customers. These arguments are unavailing at this stage.

First, McKesson contends that the underlying information was available for free, and therefore, the tools did not have "value" under the AKS. This is too narrow a view of what McKesson claims to have offered to the oncology practices. The complaint does not merely allege that McKesson provided raw data to oncology practices so that those practices could perform their own financial analyses. Rather, McKesson purportedly created the Margin Analyzer and Regimen

Profiler in order to integrate data from multiple sources—McKesson's prices, reimbursement rates from multiple insurers, including Medicare, and the practices' drug usage by dose—and synthesized that data in a manner useful to its customers. In addition to creating the tools, McKesson also updated them on a quarterly basis. Perhaps the practices could have undertaken this process on their own by creating their own spreadsheets and formulas, downloading the public data on a quarterly basis, and compiling it into a readable format. But due to lack of time, resources, or expertise, customers chose to have McKesson perform these services for them. Some purportedly chose McKesson over other lower cost providers because of these services. *See id.* ¶ 64. That practices saw value in these tools is underscored by McKesson's internal assessment of the Margin Analyzer as the "the single most important, and most valuable, tool for McKesson to win new business and maintain its existing customers." *Id.* ¶ 107.

Moreover, McKesson offered more than the data itself; it allegedly instructed its employees to identify key areas of improvement for the practices, and its employees met with practices on a quarterly basis to discuss their findings. It is no accident that McKesson wanted practices to view McKesson as a "'consultant' that can help them increase profit," *id.* ¶ 64, because Hart alleges the BDEs and Account Executives were, in essence, performing consulting work "for which a physician practice might otherwise pay a practice-management consultant," *id.* ¶ 101. In sum, the overall value of the tools and consultations was greater than the value of the underlying data itself.

Second, the Margin Analyzer, Regimen Profiler, and connected services offered more than speculative cost-savings; as alleged, the tools themselves had value. One division of McKesson provided the Margin Analyzer and Regimen Profiler in a package of business-management tools in exchange for a percentage of a practice's overall revenue. *Id.* ¶ 105. That those same tools were offered for free to commitment program customers gives rise to a plausible inference that the tools

had value. Furthermore, McKesson is alleged to have stated, in internal communications, that there were customers who stayed with McKesson, over lower cost providers, because if they left they would lose access to the Margin Analyzer. *Id.* ¶ 64.[7] McKesson purportedly created a promotional video using testimonials by customers who emphasized that the tools enhanced the financial success of their practices. *Id.* ¶ 109. Although the Court agrees that the monetary value of the tools cannot be measured by the amount of cost-savings they offered customers, the complaint contains sufficient allegations to support an inference that the tools themselves had inherent value.

Finally, although a somewhat closer question, Plaintiff has plausibly alleged that the tools were "independent" of the products sold by McKesson. McKesson contends that where the use of a service is "'tied to the product purchased," there is no independent value. Defs.' Mem. at 19 (quoting *U.S. ex rel. Forney v. Medtronic, Inc.*, No. CV 15-6264, 2017 WL 2653568, at *4 (E.D. Pa. June 19, 2017) ("*Forney*")). The critical distinction, however, is not whether the service is merely connected with, or "tied to," the product, but rather whether the service is "part of" the product itself, such that it cannot be considered to be something of value in its own right. In an advisory opinion, OIG explained this distinction as follows:

> Drug manufacturers often offer free assistance to physicians and other providers by serving as a clearinghouse for information regarding insurance coverage criteria and reimbursement levels for their products. Since these services have no independent value to providers apart from the products, they are properly considered part of the products purchased and their cost is already included in the products' price. Therefore, standing alone, these services have no substantial independent value and do not implicate the Federal anti-kickback statute.

[7] At oral argument, Defendants argued that the Court should not conflate McKesson's "internal exhortations," of the tools' value with their actual value, but that distinction is unavailing. Oral Argument Tr. at 11-12. The "value" ascribed to the tools by McKesson internally is of course not dispositive of whether a tool has "value" under the AKS. But, the allegation that employees were required to emphasize these tools to potential customers may nonetheless support a plausible inference that the tools had value, as it does here. At the pleading stage, where the Court must draw all inferences in Plaintiff's favor, these allegations provide support for Plaintiff's overall contention that the tools were "something of value."

OIG Advisory Opinion No. 00-10, 2000 WL 35747420, at *4. In that opinion, OIG went on to explain that even services that are integral to the products, such as pre-qualification of patients for coverage and reimbursement, can still implicate the AKS if combined with other services that "conferred an independent benefit." *Id.* ("For example, coupling a reimbursement support service with a program either requiring payment for ordered products only if the referring provider is paid or guaranteeing a minimum 'spread' between the purchase price and third-party reimbursement levels would implicate the anti-kickback statute."). Under this framework, a computer that can only print lab results would not constitute remuneration because it is "part of" the product itself, whereas an ordinary personal computer could constitute remuneration. *See* 56 Fed. Reg. 35952, 35978; *see also* OIG Advisory Opinion No. 10-04, 2010 WL 1937992, at *3.

Although it is true that the tools enhanced customers' experiences in purchasing drugs from McKesson and McKesson used these tools as part of its business relationship with its customers, it is not the case that these tools would have been "virtually meaningless" to customers who did not purchase drugs from McKesson. In fact, that contention is contradicted by the allegation in the complaint, which the Court accepts as true, that at least one practice requested continued access to the tools after ending its commitment program. *See* Am. Compl. at 70. While the tools may have had more utility to customers who were part of the commitment programs and were able to benefit from McKesson's quarterly updates and consultations, it is plausible that these tools had value to oncology practices regardless of whether they were active McKesson customers.

The business-management tools and quarterly consultations are also distinguishable from the types of typical product support services OIG describes in its 2003 Guidance. *See* OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23735, 2003 WL 2010428 (May 5, 2003) (describing product support services as "billing assistance

tailored to the purchased products, reimbursement consultation, and other programs specifically tied to support of the purchased product") ("2003 OIG Guidance"). These tools are not analogous to, for example, software that aids physicians in reordering and accessing records of their patients' prescription medication, *see* OIG Adv. Op. No. 12-19, 2012 WL 7148095, at *6-*8, or general product support, *see United States ex rel. Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711, 724 (N.D. Ill. 2020) ("*Suarez II*") (discussing scope of permissible product support). Instead, they are data-driven tools that customers used, with the help of McKesson representatives, to make financially optimal purchasing choices. If the tools in question had an intrinsic connection to the drug purchases, or would be of no use to oncology practices that did not buy drugs from McKesson, that might dictate a different result. As pled, however, these additional services are not so related to McKesson's drug offerings that they can be said to be integral to the products themselves or without "independent value."

An examination of the facts in the *Forney v. Medtronic* case, on which Defendants rely, is instructive. *See* 2017 WL 2653568. There, the products at issue were heart implants, and Medtronic offered services such as "free surgical support, implant device follow-up" and "free staff [at] clinics" to check the status of the implanted devices. *Id.* at 2. According to the complaint in that case, Medtronic even sought to hire staff that could "scrub in on surgical procedures," in order to "represent Medtronic during surgeries" and provide technical assistance. *Id.* Free staff who check the status of heart implants is of no value to a physician who has not purchased any heart implants. A spreadsheet that helps oncology practices track which drugs will generate the greatest profits, on the other hand, is not so integral to the product itself and thus not akin to the various support services at issue in *Forney*.

For these reasons, even using the "substantial and independent value" standard urged by Defendants, the complaint still contains sufficient facts to establish that the Margin Analyzer and Regimen Profiler constitute remuneration.

C. Judicial Notice of the Purportedly Similar Tools

Finally, McKesson's attempt to call into question the value of the tools by comparison to similar tools published by other entities, is, at this stage, inappropriate. McKesson seeks to have the Court take judicial notice of tools offered by national associations such as the American Society of Clinical Oncology, other pharmaceutical distributors like Cardinal Health, and online health care entities such as NantHealth or Via Oncology. McKesson alleges that each of these entities offered tools that provided the same services as the Margin Analyzer and Regimen Profiler. According to McKesson, "if the physician office can get the business analytical tools for free off the Internet, or easily from other distributors, then [the business-management tools] cannot provide substantial value." Defs.' Mem. At 18; *see also* Oral Argument Tr. at 10.

Federal Rule of Evidence 201 permits a court to take judicial notice of a fact that "is generally known within the trial court's territorial jurisdiction; or can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b). "Because the effect of judicial notice is to deprive a party of the opportunity to use rebuttal evidence, cross-examination, and argument to attack contrary evidence, caution must be used in determining that a fact is beyond controversy under Rule 201(b)." *Finn v. Barney*, 471 F. App'x 30, 32 (2d Cir. 2012) (quoting *Int'l Star Class Yacht Racing Ass'n v. Tommy Hilfiger U.S.A., Inc.*, 146 F.3d 66, 70 (2d Cir. 1998)).

Courts may take notice of public information in adjudicating a motion to dismiss without converting that motion to a summary judgment motion. *See Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 426 (2d Cir. 2008). McKesson, however, is not seeking for the Court to take

notice of an incontrovertible fact, but rather, for it to evaluate a plethora of other "business analytical tools" and determine that those tools are substantially the same as the tools offered by McKesson. That is well beyond the sort of straightforward information of which courts routinely take judicial notice. *See, e.g., United States v. Michael*, 664 F. App'x 32, 36 (2d Cir. 2016) (holding that the district court did not abuse its discretion in taking judicial notice of the relationship between Eastern Standard Time and Coordinated Universal Time); *Finn*, 471 F. App'x at 32; *United States v. Kelly*, 368 F. App'x 194, 199 (2d Cir. 2010) (taking judicial notice of a guilty plea); *see also* Advisory Committee Notes to 1972 Proposed Rules, Fed. R. Evid. 201(b) ("With respect to judicial notice of adjudicative facts, the tradition has been one of caution in requiring that the matter be beyond reasonable controversy."). While McKesson cites several cases in support of its argument, those cases, involving straightforward factual information, stand in stark contrast to the judicial notice it seeks here. *See Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1092 (2d Cir. 1995) (taking judicial notice of guilty pleas); *Doron Precision Sys., Inc. v. FAAC, Inc.*, 423 F. Supp. 2d 173, 179 (S.D.N.Y. 2006) (taking judicial notice of statements made on Plaintiff's website); *Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 166 (S.D.N.Y. 2015) (taking judicial notice of documents sourced from government websites, electronic databases, and information on the company's website that was "capable of accurate and ready determination"). McKesson's remaining cases are distinguishable because they involve notice of the mere fact that public information existed, without relying on the substance of the underlying information. *See New Jersey Carpenters Health Fund v. Royal Bank of Scotland Grp., PLC*, 709 F.3d 109, 127 n.11 (2d Cir. 2013) (stating that courts may take judicial notice of "the *fact* that press coverage contained . . . certain information so long as they do not rely on the truth of that information"); *Staehr v. Hartford Fin. Servs. Grp., Inc.*, 547 F.3d 406, 425 (2d Cir. 2008)

(The court did "not take judicial notice of the documents for the truth of the matters asserted in them, but rather to establish that the matters [had] been publicly asserted.").

Here, McKesson is not merely asking for the Court to take judicial notice that other tools existed. Rather, McKesson's request that the Court take notice of these "obvious comparators," requires a fact-based comparison of those tools to the Margin Analyzer and Regimen Profiler. Such an inquiry is not within the Court's purview, especially not on a motion to dismiss. *See Kelly-Brown v. Winfrey*, 717 F.3d 295, 313 (2d Cir. 2013) ("Our role in considering a motion to dismiss is not to resolve these sorts of factual disputes.").

The Second Circuit has cautioned that "the more critical an issue is to the ultimate disposition of the case, the less appropriate judicial notice becomes." *Pina v. Henderson*, 752 F.2d 47, 50 (2d Cir. 1985). That warning is apt here, where McKesson seeks a determination that the offering of similar tools for free demonstrates that McKesson's tools did not have any value. McKesson may ultimately prevail by using these comparator tools to demonstrate that equivalent tools were offered for free, but the Court declines to conclude as much now by taking judicial notice of a disputed fact—that the comparators are not only similar but obviously so—on a motion to dismiss.

Accordingly, Hart's complaint adequately alleges that the tools constituted remuneration.

II. Hart Has Failed to Plausibly Allege that McKesson Acted with the Requisite Scienter

The AKS prohibits a person from "knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) . . . to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made . . . under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Hart

is not only required to plead that McKesson offered these tools to its customers, but that it did so with a culpable mental state.

A. The Scienter Requirement of the AKS

There is no dispute that any violation of the FCA must be done knowingly, but where an FCA claim is based on a violation of the AKS, the AKS scienter requirement must also be satisfied. The parties disagree as to what mental state is required to allege a "willful" violation. Plaintiff argues he must plead only "that the defendant willfully committed an act that violated the Anti-Kickback Statute." Pl.'s Mem at 18 (quoting *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013)). McKesson, however, asserts that willfulness requires McKesson to have acted "with an intent to do something unlawful." Defs.' Reply at 9.

Willful is a "word of many meanings," and its construction is influenced by the context in which it is used. *Ratzlaf v. United States*, 510 U.S. 135, 141 (1994). The Supreme Court has distinguished, for example, a "willful violation of the tax laws," which requires a finding that the defendant was aware of a specific provision of the tax code he was charged with violating, from the "traditional rule" that willfulness requires only "knowledge that the conduct is unlawful." *See Bryan v. United States*, 524 U.S. 184, 194-96 (1998). In the context of the AKS, "courts have observed that 'interpreting the *mens rea* requirement of the Anti-Kickback Statute has yielded different results.'" *Bilotta*, 50 F. Supp. 3d 497, 514 n.6 (S.D.N.Y. 2014) (quoting *U.S. ex rel. Bartlett v. Ashcroft*, 39 F. Supp. 3d 656, 678 n.18 (W.D.Pa. Aug. 21, 2014)). The Second Circuit was presented with an opportunity to evaluate the meaning of willfulness in the AKS in 2002, when a defendant questioned on appeal whether in a "prosecution for a violation of the Medicare anti-kickback statute, the Government is required to prove that the defendant knew of and intended to violate that specific statute." *United States v. Mittal*, 36 F. App'x 20, 21 (2d Cir. 2002). In *Mittal*, the district court had instructed the jury that

> 'Willfully' means to act with knowledge that one's conduct is unlawful and with the intent to do something that the law forbids, that is to say with the bad purpose to disobey or to disregard the law. To find that the defendant acted willfully, you must find that he knew what he was doing was illegal, although he need not have known the specific statute he may have been violating. The defendant's conduct was not willful if it was due to negligence, inadvertence, or mistake.

Id. at 21. Rather than resolve the "lack of unanimity among the other Circuits" on whether the district court's instruction was proper, or whether willfulness in this context required a specific intent to violate the AKS, the Second Circuit found that any error in the instruction was harmless because the defendant's actual knowledge of the AKS had been established at trial. *Id.* at 21-22.

The circuit split referenced by the court in *Mittal* was resolved in 2010 by the Patient Protection and Affordable Care Act (PPACA), which added the following language to the AKS:

> Actual knowledge or specific intent not required: with respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

42 U.S.C. § 1320a-7b(h). Following this amendment, most courts have understood the term willfully, as used in the AKS, as following the "traditional rule" that "knowledge that the conduct is unlawful is all that is required." *See Bryan*, 524 U.S. at 196. Although neither party has cited Second Circuit authority squarely addressing the scope of the willfulness requirement after the 2010 amendment, at least one court in the Eastern District has expressly adopted this definition. *United States v. Novartis AG*, No. 04-CV-4265 (NGG) (RLM), 2011 WL 13234720, at *9 (E.D.N.Y. Feb. 8, 2011) (holding that in order to "meet the AKS's 'willfulness' requirement" the defendant must have "act[ed] with the intent to do something that the law forbids."). Application of the so-called "traditional rule" also accords with *Mittal*. *See* 36 F. App'x at 21. The majority of circuit courts to have addressed this issue, both before and after the 2010 amendment, have similarly recognized that the term "willfully" requires knowledge that the relevant conduct is unlawful. *See United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 33

(1st Cir. 1989); *United States v. Goldman*, 607 F. App'x 171, 174-75 (3d Cir. 2015); *United States v. Nagelvoort,* 856 F.3d 1117, 1126 (7th Cir. 2017) *cert. denied* 138 S.Ct. 556 ("[Defendants] contend that the evidence presented at trial was insufficient to prove that they knowingly or willfully violated the Anti-Kickback Statute when they entered into the arrangements at issue. Again, however, there was sufficient evidence from which the jury could have concluded that both appellants knew the contracts were illegal."); *United States v. Jain*, 93 F.3d 436, 441 (8th Cir. 1996) ("In the Medicare anti-kickback statute, the word "willfully" modifies a series of prohibited acts. Both the plain language of that statute, and respect for the traditional principle that ignorance of the law is no defense, suggest that a heightened *mens rea* standard should only require proof that Dr. Jain knew that his conduct was wrongful, rather than proof that he knew it violated 'a known legal duty.'"); *United States v. Sosa*, 777 F.3d 1279, 1293 (11th Cir. 2015) ("In order to find that a person acted willfully in violation of § 1320a–7b, the person must have acted voluntarily and purposely, with the specific intent to do something the law forbids, that is with a bad purpose, either to disobey or disregard the law. However, the defendant need not have known that a specific referral arrangement violated the law."). While these decisions are not binding, the Court is persuaded that willfulness in the AKS requires a defendant to have acted with knowledge that its conduct was unlawful.

This holding is further supported by the legislative history of the 2010 amendment, which indicates that its purpose was to clarify that actual knowledge of the statute was *not* required, and that willfulness in this context only required the defendant to know its conduct was unlawful. *See* 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (statement of Rep. Kaufman discussing predecessor bill to PPACA, the Health Care Enforcement Act of 2009) ("The Ninth Circuit Court of Appeals has read the term to require proof that the defendant not only intended to engage in

unlawful conduct, but also knew of the particular law in question and intended to violate that particular law. This heightened mental state requirement may be appropriate for criminal violations of hyper-technical regulations, but it is inappropriate for these crimes, which punish simple fraud."); *see also United States v. Shvets*, 631 F. App'x 91, 95-96 (3d Cir. 2015) *cert. denied* 136 S. Ct. 1526 (2016) (discussing legislative history in the context of the health care fraud statute). In sum, the complaint must at least give rise to a plausible inference that McKesson knew its conduct was unlawful, but Hart need not allege actual knowledge of the AKS or specific intent to violate it.

Hart argues for an even lower standard, based on the Fifth Circuit's holding in *United States v. St. Junius*—that "willfulness" requires only that the conduct was not negligent or accidental. 739 F.3d at 210; Pl.'s Opp at 18 ("[T]he statute's intent element distinguishes negligent or accidental conduct, which is innocent, from willful conduct, which is culpable."). In *St. Junius*, the Fifth Circuit held that the "the Government must prove that the defendant willfully committed an act that violated the Anti-Kickback Statute." *St. Junius*, 739 F.3d at 210. In so doing, it distinguished its holding from the heightened standard articulated by the Ninth Circuit in *United States v. Dearing*, 504 F.3d 897 (9th Cir. 2007):

> *Dearing* holds that the willfulness component of 18 U.S.C. § 1347 (which is not the Anti-Kickback Statute, but rather, a general health care fraud statute) requires that the government prove that the defendant acted with knowledge that her conduct was unlawful. *Dearing*, however, was decided prior to a statutory amendment that clarified Congress' intent with respect to the willfulness element of § 1347. Section 1347 was amended in 2010 as was 42 U.S.C. § 1320a–7b, the Anti-Kickback Statute. The § 1347 amendment adds language that mirrors the 2010 amendment to the Anti-Kickback Statute found in § 1320a–7b(h). Section 1320a–7b(h) made clear that the government need not prove that the defendant had "actual knowledge of the statute or a specific intent to violate the statute." In light of the amendment, *Dearing* is unpersuasive on this issue.

St. Junius, 739 F.3d at 210 n.19. Subsequent Fifth Circuit cases, however, have applied the traditional rule in the AKS context, which calls into question how *St. Junius* fits into the Fifth Circuit's "willfulness" jurisprudence. *See United States v. Nora*, 988 F.3d 823, 830 (5th Cir. 2021) ("Although the precise meaning of the term "willfully" can vary depending on the context . . . this court has held that the general understanding of the term applies to its use in the general health care fraud statute and the health care anti-kickback statute."); *see also United States v. Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) ("Under this definition of willfulness, 'knowledge that the conduct is unlawful is all that is required.'"). And, at least one court has drawn the distinction proposed by Plaintiff's counsel at oral argument, that the level of intent required depends on whether the charge is a criminal AKS violation or a civil FCA violation based on an AKS as violation. *See* Oral Argument Tr. at 28, *see United States v. Marlin Med. Sols. LLC*, No. SA-5:21-CV-00160 (OLG), 2022 WL 190308, at *4, *4 n.2 (W.D. Tex. Jan. 12, 2022). There is some support in the Fifth Circuit for Plaintiff's reading of *St. Junius*, *see United States v. Waller*, No. CR H-14-171-11, 2017 WL 2559092, at *6 (S.D. Tex. June 13, 2017), *aff'd*, 741 F. App'x 267 (5th Cir. 2018), but at least one court has cited *St. Junius* while still applying the traditional rule in the AKS context, *United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 656 (N.D. Tex. 2020) ("To act 'willfully' is to act 'with the specific intent to do something the law forbids' . . . However, 'a person need not have actual knowledge of' the AKS 'or specific intent to commit a violation of' the AKS." (first quoting *United States v. Gibson*, 875 F.3d 179, 188 (5th Cir. 2017) and then quoting 42 U.S.C. § 1320a-7b(h) and citing *United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013))).

Even if the Court accepts Plaintiff's reading of *St. Junius*, the decision is not binding here, and the Court is not persuaded the holding is mandated by the 2010 amendment. Indeed, the more persuasive view is that of the numerous circuit courts which have continued to follow the

traditional rule after the 2010 amendment. *See supra* pp. 24-25. Moreover, several courts have applied the traditional definition after the 2010 amendment in civil cases where an AKS violation is a predicate for an FCA claim. *United States ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106, 1113 (N.D. Ill. 2018) ("Defendants also insist that relator has not pled the scienter required for an AKS violation. The statute's willfulness requirement indeed means that relator must allege that defendants had at least some 'bad purpose . . . to do something that the law forbids.'" (alteration in original)); *see also United States v. Teva Pharms. USA, Inc.*, No. CV 20-11548 (NMG), — F.Supp.3d —, 2021 WL 4132592, at *6 (D. Mass. Sept. 9, 2021); *United States ex rel. Ani Gharibian et al. v. Valley Campus Pharmacy, Inc.*, No. 2:16-CV-4777 (MCS) (PLA), 2021 WL 4816648, at *13 (C.D. Cal. June 23, 2021) ("[T]o establish willfulness, the [relator] must prove that defendants knew their conduct was unlawful." (alteration in original)); *Suarez II*, 503 F. Supp. 3d at 735; *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, No. CV 12-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); *United States ex rel. Scarlett Lutz et al. v. Berkeley Heartlab, Inc.*, 225 F. Supp. 3d 487, 498, 510-11 (D.S.C. 2016); *see also United States v. Mathur*, No. 2:11-CR-00312 (MMD), 2012 WL 4742833, at *5 (D. Nev. Sept. 13, 2012), report and recommendation adopted, 2012 WL 4711960 (D. Nev. Oct. 3, 2012) (discussing effect of 2010 amendment on circuit split).

Accordingly, to satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful, although he need not allege it acted with specific knowledge of the AKS.

B. Hart's Allegations Regarding McKesson's Scienter

As noted above, unlike the "circumstances constituting fraud," which must be pled with particularity, Rule 9(b) only requires that intent or knowledge be "alleged generally." Fed. R. Civ. P. 9(b). Nonetheless, the complaint must contain some factual allegations from which the Court

can infer Defendants acted with the knowledge that their conduct was unlawful. *See United States ex rel. Suarez v. AbbVie Inc.*, No. 15-CV-8928, 2019 WL 4749967, at *13-*14 (N.D. Ill. Sept. 30, 2019) ("*Suarez I*"); *see also Forney*, 2017 WL 2653568, at *4-*5. Any such allegations are lacking here.

Hart has alleged that McKesson's contracts, code of conduct, and SEC filings indicated an awareness of the requirements of the AKS and the general unlawfulness of inducements. Am. Compl. ¶¶ 111-12. McKesson's internal policies, for example, prohibited employees from providing of "things of value" to induce purchases of items that would ultimately be reimbursed by government sponsored health care providers. *Id*. Hart has also alleged facts to support the conclusion that the tools may constitute "remuneration" under the broad language of the AKS. *See supra* Section I.B. Allegations that McKesson knew remuneration to induce purchases was prohibited in general, however, cannot alone support a finding that McKesson knew this particular course of conduct was unlawful. In other words, absent from his complaint are any allegations from which the Court can plausibly infer that McKesson knew providing these tools to commitment program customers was unlawful. Without such allegations, Hart fails to state a claim.

The complaint here lacks allegations of the type that courts have found to support an inference of scienter, such as actions taken to conceal the fraudulent scheme, *Suarez II*, 503 F. Supp. 3d at 735; *United States ex rel. Strunck v. Mallinckrodt Ard LLC*, No. CV 12-175, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020); notice from counsel that the program may be unlawful, *United States v. Teva Pharms.,* 2021 WL 4132592, at *6; *United States v. Millennium Radiology, Inc.*, No. 1:11-CV-825, 2014 WL 4908275, at *8 (S.D. Ohio Sept. 30, 2014); *United States ex rel. Banigan v. Organon USA Inc.*, No. CV 07-12153 (RWZ), 2016 WL 10704126, at *3 (D. Mass.

Aug. 23, 2016) (internal document characterizing relationship as a "quid pro quo" was sufficient to establish dispute as to scienter at summary judgment stage); cancellation of the program due to concerns over its lawfulness, *Wood*, 246 F. Supp. 3d at 829; or a service without legitimate value that was a pretext to provide remuneration, *United States v. TEVA Pharms. USA, Inc.*, No. 13-CV-3702 (CM), 2016 WL 750720, at *28 (S.D.N.Y. Feb. 22, 2016) (describing company-sponsored speaker programs as "shams"). According to Plaintiff's own allegations, it appears the program was openly advertised and widely discussed both within the company and among its customers. *See Novartis*, 2011 WL 13234720, at *9 ("Plaintiffs do not allege any facts, circumstantial or otherwise, that Novartis believed, or acted in a way suggesting it believed, that its marketing . . . was illegal. Rather, and in contrast to other cases where the courts have found sufficiently pleaded AKS claims, Plaintiffs' amended complaint suggests Novartis allegedly paid kickbacks to physicians quite openly."). Hart's complaint is lacking even general allegations which suggest that McKesson knew that offering the tools to commitment program customers was unlawful—indeed, his description of McKesson's conduct arguably suggests the opposite. *United States v. Valley Campus Pharmacy, Inc.*, No. 2:16-CV-04777 (MCS) (PLA), 2021 WL 5406148, at *3 (C.D. Cal. Oct. 12, 2021) *appeal filed* No. 21-56253 (Nov 16, 2021) ("Relator never alleges, even generally, that Defendants knew that their offer of free PA services was unlawful. In fact, Relator's allegations seem to indicate that Defendants thought their offering of PA services was lawful, as they advertised these services openly on their website and in a presentation in Las Vegas.").

In sum, identifying a policy that plausibly violates the AKS and alleging that a defendant had a general awareness of the laws regulating the pharmaceutical industry is not enough to establish scienter. There must be facts from which the Court can infer that Defendants knew the conduct was unlawful and proceeded with the business practice regardless. *See Forney*, 2017 WL

2653568, at *4-*5 ("[Relator alleged] that the effect of the scheme was to induce physicians to refer Medtronic's products to their patients, [but had] not alleged that its subjective purpose was to do so."). Hart's complaint lacks any such non-conclusory allegations as to scienter, and accordingly, his claims must be dismissed.

III. Had Hart Alleged Scienter, His Complaint Would Have Sufficed to Allege the Submission of False Claims

The Second Circuit has held that alleging "fraud under the FCA [requires] two components: the defendant must submit or cause the submission of a claim for payment to the government, and the claim for payment must itself be false or fraudulent." *Chorches*, 865 F.3d at 83 (quoting *Hagerty ex rel. U.S. v. Cyberonics, Inc.*, 844 F.3d 26, 31 (1st Cir. 2016)). McKesson argues that the complaint is deficient because it neither "identif[ies] a single false claim, nor does it allege facts that allow the court to 'adduce specific facts supporting a strong inference of fraud.'" Defs.' Mem. at 22 (quoting *Chorches*, 865 F.3d at 82). Due to the absence of facts supporting an inference of scienter, Hart has failed to plausibly allege a fraud, although his complaint does contain allegations sufficient to support an inference that claims were ultimately submitted to the government.

To allege that claims were submitted to the government, a plaintiff does not need to possess "specific identified false invoices." *Chorches*, 865 F.3d. at 86. Instead, "a complaint can satisfy Rule 9(b)'s particularity requirement by making plausible allegations creating a strong inference that specific false claims were submitted to the government and that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *Id.* at 86; *see also United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 248 (2d Cir. 2019).

Although the bills and invoices here were not "peculiarly within the knowledge" of the Defendants, as they were in *Chorches*, they were outside of Hart's purview nonetheless. In his capacity as a BDE, Hart cannot be expected to have had access to the oncology practices' bills or other evidence related to the actual submission of claims. Hart instead relies on the records available to him—in particular, the Margin Analyzer reports provided to Summit Cancer Care over several quarters (Q2 2012, Q4 2012, Q1 2013)—and his allegations support a plausible inference that McKesson knew its customers were routinely submitting claims to Medicare and other federal health care programs. The data reported in Summer Cancer Care's Margin Analyzer spreadsheets demonstrates that many of the submissions for reimbursement were made to Medicare. *See* Q4 2012 SCC Margin Analyzer; Q1 2013 SCC Margin Analyzer. That its employees regularly updated the tools with the newest CMS schedules also supports an inference that McKesson knew its customers were likely to submit claims to Medicare, as those schedules are primarily relevant to Medicare beneficiaries. Moreover, the primary utility of the Margin Analyzer and Regimen Profiler was the ability to highlight cost-savings based on comparison of acquisition costs to reimbursement rates of various insurers, including Medicare. These allegations support a "strong inference" that the practices named in the complaint which were provided the Margin Analyzer and Regimen Profiler actually submitted claims for reimbursement to federal health care programs.

Defendants argue that Hart's complaint contains less substantive allegations as to the submission of these claims than a complaint the Second Circuit recently held was insufficient in *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244 (2d Cir. 2019). In *Gelbman*, the Second Circuit found that the plaintiff in an FCA case had failed to plausibly allege any invoices were uniquely in the defendants' control, and also failed to plead facts that gave rise to a strong inference of fraud. *Id.* at 248. While that case is instructive, the facts are distinguishable.

The relator in *Gelbman* was an "Information Specialist," who purportedly learned of the fraud when performing work on "Medicaid management and fraud detection." *Id.* at 246. Given that role, the Circuit concluded that he would have had access to more detailed records than those referenced in the complaint. Here, by contrast, Hart would not be expected to have access to any purchase records in his role as BDE. Moreover, the complaint in *Gelbman* left the court to "speculate as to the specific design and implementation of a scheme that purportedly defrauded the federal government of more than $14 billion over the course of six years." *Id.* at 249. In particular, the Circuit criticized the lack of detail around how the fraud was carried out:

> Gelbman alleges in a conclusory fashion that his superiors at NYSDOH "conspired" with an unknown number of unidentified "HRA representatives" to "manipulate and rig" eMedNY. Gelbman does not detail how eMedNY was rigged (*e.g.*, by altering eMedNY's computer algorithms, or by making post-hoc adjustments to eMedNY payment determinations), or who carried out the rigging (*e.g.*, NYSDOH employees, City employees, or some unknown third party).

Id. at 248-49. While Hart has failed to allege McKesson acted willfully, his complaint does not leave doubt as to the nature or scope of the conduct at issue. In sum, Hart's complaint is adequate to support an inference that claims were submitted by the practices in the Southeast which Hart identified as having received the Margin Analyzer and Regimen Profiler.

Finally, McKesson argues that even if the detailed allegations regarding Summit Cancer Care support a claim as to that practice, Hart has not adequately alleged that claims were submitted by practices nationwide. Defs.' Reply at 7 ("From that one assertion, and from that one customer, Relator asks the Court to fill in the details on not only the claims submitted by Summit, none of which is identified, but for all other unidentified customers around the country."). In light of the Court's dismissal of this action, and grant of leave to amend, *see infra* Section IV, as well as the representations by Plaintiff's counsel that Hart now has additional information regarding

McKesson's conduct nationwide, *see* Oral Argument Tr. at 25-26, the Court will refrain from evaluating the sufficiency of the allegations as to the nationwide scheme at this time.

IV. Hart is Granted Leave to Amend

Although Plaintiff has not explicitly sought leave to amend, the Court nonetheless grants Plaintiff leave to file a second amended complaint to address the inadequacies discussed here, provided he has a good faith basis to do so. *See Khodeir v. Sayyed*, 323 F.R.D. 193, 197 (S.D.N.Y. 2017). Rule 15 states that "the court should freely give leave [to amend a complaint] when justice so requires." Fed. R. Civ. P. 15(a)(2). The Second Circuit has emphasized that this is a "permissive" standard, and that leave to amend should be liberally granted, consistent with the Circuit's "strong preference for resolving disputes on the merits." *Loreley Fin. (Jersey) No. 3 Ltd. v. Wells Fargo Sec., LLC*, 797 F.3d 160, 190 (2d Cir. 2015). "Ordinarily, a plaintiff should be granted leave to amend at least once after having the benefit of a court's reasoning in dismissing the complaint." *Obra Pia Ltd. v. Seagrape Inv'rs LLC*, 19-CV-7840 (RA), 2021 WL 1978545, at *3 (S.D.N.Y. May 18, 2021). This is especially true on the Court's first ruling on a motion to dismiss. *Loreley*, 797 F.3d at 190 ("Without the benefit of a ruling, many a plaintiff will not see the necessity of amendment or be in a position to weigh the practicality and possible means of curing specific deficiencies."); *see also Cresci v. Mohawk Valley Cmty. Coll.*, 693 F. App'x 21, 25 (2d Cir. 2017) ("The proper time for a plaintiff to move to amend the complaint is when the plaintiff learns from the District Court in what respect the complaint is deficient. Before learning from the court what are its deficiencies, the plaintiff cannot know whether he is capable of amending the complaint efficaciously."). With the benefit of the Court's reasoning, as well as the

numerous arguments raised by Defendants' motion to dismiss, Plaintiff may be able to cure the deficiencies in his complaint.[8]

CONCLUSION

For the reasons stated above, the motion to dismiss is granted, albeit with leave to amend. If he chooses to do so, Plaintiff may file a second amended complaint no later than June 7, 2022. The Clerk of Court is respectfully directed to terminate the motion at docket number 51.

SO ORDERED.

Dated: May 5, 2022
New York, New York

RONNIE ABRAMS
United States District Judge

[8] Defendants included a footnote in their memorandum of law in support of the motion to dismiss stating that Hart's allegations "raise significant commercial speech defenses." Defs.' Mem. at 1 n.1. "Because the arguments appear only in footnotes, they are not properly raised, and the Court is under no obligation to consider them." *See Weslowski v. Zugibe*, 96 F. Supp. 3d 308, 314 (S.D.N.Y. 2015), *aff'd*, 626 F. App'x 20 (2d Cir. 2015) (collecting cases). If Plaintiff amends his complaint, Defendants may raise this issue in full in a subsequent motion if they choose to do so.